K113670

MAY - 8 2012



# 510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 04/27/2012

1. Submission Sponsor

| | Submitter |
|---|---|
| Name | Infopia Co.,Ltd. |
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2. Submission Correspondent

LK Consulting Group
951 Starbuck St. Unit J,
Fullerton, CA 92833
Priscilla Chung
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Email: juhee.c@lkconsultinggroup.com

3. Device

- Trade Name: Element™ Blood Glucose Monitoring System
- Classification Name: Glucose test system, Quality control material (assayed and unassayed)
- Classification regulation: 21 CFR Part 862.1345, 21 CFR Part 862.1660
- Product Code: NBW, CGA, JJX

4. Predicate Device:

Element™ plus Blood Glucose Test System (K103021), Infopia Co., Ltd.

5. Description:

The Element™ Blood Glucose Monitoring System consists of the meter, test strips and control solutions (low, normal and high levels). The blood glucose test system is an in vitro diagnostic device designed for measuring the concentration of glucose in whole blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement.

6. Indications for use:

- Element™ Blood Glucose Monitoring System (For single patient-home use)

The Element ™ Blood Glucose Monitoring System is for the quantitative measurement of glucose in capillary whole blood taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh. Element ™ Blood Glucose Testing System is for in vitro diagnostic use and is not to be used for the diagnosis of or screening for diabetes or for neonatal use. Element ™ Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The Element ™ Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in the management of diabetes. Alternative site Testing (ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh) should be done during steady- state times when glucose is not changing rapidly.

The Element ™ Test Strips are for use with the Element™ Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

The Element ™ control solutions are for use with the Element ™ Blood Glucose Monitoring system to check that the meter and the test strips are working together properly and the test is performing correctly.

7. Comparison to the Cleared Device

The battery type, the location of the display icons, the raw material of the LCD, and the dimension of the meter have been changed, and the voice function has been removed. Other than these modifications, the modified meter has the following similarities to the cleared device:

- has the same intended use,
- uses the same operating principle,
- incorporates the same materials,
- adopts the same use environment and calibration method, and has the same shelf life.

8. Performance Data

Clinical: The clinical performance evaluation using the Element ™ Blood Glucose Monitoring System components were conducted for purpose of validating the consumer use for the user and the professional accuracy. Test results showed substantial equivalence.

Non-clinical: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the Element ™ Blood Glucose Monitoring System. The device passed all of the tests based on pre-determined Pass/Fail criteria.

Disinfection Study: Disinfectant CaviWipes with the EPA registration number of 46781-8 has been validated demonstrating complete inactivation of live virus of use with the meter and the reusable lancing device. There was also no change in performance or in the external materials of the meter and the lancing device after 1,095 cleaning/disinfection cycles designed to simulate 3 years of device use.

9. Conclusion

The conclusion drawn from the clinical and nonclinical tests is that the Element ™ Blood Glucose Monitoring System is as safe, as effective and performs as well as the legally marketed predicate device, Element ™ plus Blood Glucose Test System (K103021).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Infopia Co., Ltd.
c/o Priscilla Chung
951 Starbuck St, Unit J
Fullerton, CA 92833

MAY - 8 2012

Re: k113670
Trade Name: Element blood glucose monitoring system
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: April 6, 2012
Received: April 12, 2012

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indication for Use

**510(k) Number** (if known): K113670

**Device Name:** Element™ Blood Glucose Monitoring System

**Indication For Use:**

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The Element ™ Test Strips are for use with the Element™ Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

The Element ™ control solutions are for use with the Element ™ Blood Glucose Monitoring system to check that the meter and the test strips are working together properly and the test is performing correctly.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ___√ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) K113670